LONG-COVID AND THE NIH RECOVERY INITIATIVE: THOUGHTS ON CLINICAL "STUDIES"

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ELEMENTS COMMON TO MOST STUDIES

RegenMed has had the honor of working with providers and industry around the world for many years on studies and trials. Several broad themes emerge:

- Clinical Burden: Most providers wish to conduct studies. Virtually all product manufacturers must regularly conduct studies.
- However, time requirements, cost and design/execution complexity make traditional studies prohibitively expensive for all but the best capitalized entities.
- Restrictive inclusionary and exclusionary criteria in study populations render most study results of questionable value for the majority of patients.
- Ownership of, and access to, study data are often delayed and/or restricted.
- Most studies are terminated prematurely or, if "completed", do not in fact result in statistically significant, auditable datasets.
- Most studies which fail to reach positive are not published.
- What most providers, patients, regulators, and payers are looking for in studies is everyday clinical decision support. Remarkably few studies provide this support.

RE-THINKING STUDY FORMATS

National authorities recognize the negative impact on broad healthcare metrics of over-reliance on traditional forms of medical studies. The European Medicines Agency and the U.S. FDA have stressed the importance of real-world data and evidence.

Similarly, the AHRQ publication Registries For Evaluating Patient Outcomes provides an independent and thorough review of efficient study formats. The

21st Century Cures Act, Right To Try Act and similar legislative initiatives are designed to expedite the availability of safe and efficacious treatment protocols and products. This means, necessarily, improving the efficiency and lowering the costs of trials and other studies.

The U.S. government's recently announced RECOVER initiative represents a major validation of the importance of more pragmatic study formats. RECOVER builds upon and expands a $1 billion "long-COVID" research initiative already underway at the U.S. National Institutes of Health. It encompasses several key elements of modern approaches to studies:

Scale:	Intends to sign up 48,000 individuals with and without long-COVID symptoms.
Regular Reports:	First one scheduled for later in 2023.
Purpose:	Development of evidence-based best practices and guidance for providers and patients. Development of Centers of Excellence to develop templates for care.
Reimbursement:	Provide datasets needed to support reimbursement by government and private payers.
Patient Focus:	The primary goal of RECOVER, its studies and its research are improving health of long-COVID patients (estimated in the millions in the U.S. alone).
Patient Cohorts:	Distinguish among specific patient groups (age-based, race-based, etc.) in terms of symptoms, etiologies, treatment protocols.
Research:	Answer long-unanswered questions on systemic causes underlying the wide variety of symptoms.

GOING FORWARD

There will always be legitimate needs for randomized, controlled, double-blinded clinical trials. However, their cost and narrow scope – virtually all are now industry sponsored – implies little genuine support in everyday clinical decision-making. As the foregoing governmental initiatives imply, there are often other equally valuable study approaches with greater benefits to broader patient populations.

There can be little question that contemporary technology, better clinician and patient user experiences, and thoughtful study designs can support clinical decision-making leading to better outcomes across much larger population groups.

Circles are designed precisely to enable such studies of any scale or complexity -- in a turnkey, clinical-grade, and low-cost manner. Please contact us to find out more.
